DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

SEP 28 1999

WARNING LETTER

Mr. Ian Lomas
Managing Director/CEO
Surgical Innovations, Ltd.
Clayton Park, Clayton Woodrise
Leeds W-Yorkshire
England LS16-6RF

Dear Mr. Lomas:

During an inspection of your firm located in Leeds W-Yorkshire, England on July 22, 1999, our investigator determined that your firm manufactures laparoscopic surgical devices. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below.

1. Failure to establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product including setting forth the review and disposition process, the documentation of the disposition of nonconforming product, the justification for use of nonconforming product, and the signature of the individual(s) authorizing the use, as required by 21 CFR 820.70(b). For example, the GI Receiving Inspection Form (QA22) for the Reducer Seal Holders on the YelloPort device documents that on 3/31/99, 258 components, batch 10678, failed testing and were rejected. The Production Permit/Concession Form (QA08) shows that this component, batch 10678, was used in production but does not state the justification for using the nonconforming product.

2. Failure to hold finished devices in quarantine, until released, and to not release the devices for distribution until the activities required in the device master record are completed, as required by 21 CFR 820.80(d)(1). For example:

   a. No leak tests and measurements are performed on finished devices to assure the YelloPort devices meet specifications.

b. SOP IP005006 does not include conducting a leak test nor measuring critical dimensions on the YelloPort devices for the cannulas.

c. SOP IP005003 does not include measuring critical dimensions on the YelloPort trocar devices.

3. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record and the requirements of this part including or referring to the location of the primary identification label and labeling used for each production unit, as required by 21 CFR 820.184. For example, no labeling is retained with the device history records from each lot of manufactured YelloPort devices. The white sticker labels that go on the device carton and the corresponding booklet labeling give the directions for use.

4. Failure to review, evaluate, and investigate any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications, unless such investigation has already been performed for a similar complaint and another investigation is not necessary, as required by 21 CFR 820.198(c). For example:

a. All complaints have not been reviewed and evaluated to determine whether an investigation is necessary. Oral and written complaints/repairs are not always evaluated as formal complaints. If a customer complains about a device but does not request that it is to be registered as an official formal complaint, then the complaint is not recorded or evaluated as a complaint. It is treated as a repair.

b. Complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications are not investigated where necessary. A YelloPort device was returned for repair and there is no documentation that the cracked sheath tube was investigated as part of the complaint handling system.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes

are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all devices manufactured by Surgical Innovations, Ltd., Clayton Park, Clayton Woodrise, Leeds W-Yorkshire, England may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide responses to the charges in this Warning Letter for our review. After we notify you that the response is adequate, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections has been verified, your products may resume entry into this country.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter.

If documentation is not in English, please provide an English translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Sincerely yours,

Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health